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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,615	08/25/1999	EDWARD L. SINOFKY	101327-126	5467
21125	7590	11/01/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/382,615

Applicant(s)

SINOFSKY, EDWARD

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-12, 15, 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven. Kittrell et al teach a device as claimed except for the particular deflection member. Heaven teaches a deflection member (see figure 1) which has an outer sheath (14), a cut out and, when viewed in profile, an hourglass shape wherein the width of the cut away portion is less than the diameter of the non-cut away portion. It would have been obvious to insert the device of Kittrell et al into the device of Heaven or to employ the elongate and the deflection member of Heaven in the device of Kittrell et al in place of, for example, element 140 in figure 14, since Kittrell et al envision a wide variety of deflection mechanisms; to provide multiple deflection members to allow deflection in multiple directions; and to form the deflection member so as to run from the proximal end of the catheter, since this would provide greater strength as shown by Heaven, thereby rendering the cutout at the distal end of the deflection member, and to form the member or surround the member with a fluoropolymer, since these are notorious for use in catheters and provide a lubricious surface, official notice which has already been taken, and to provide the particular location of the cutout, since this is not critical and provides no unexpected result, thus producing a device such as claimed.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaven in combination with Kittrell et al. The teachings of Heaven and Kittrell et al and the motivation for modification and combination thereof are essentially those already set forth above. It would have

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been obvious to the artisan of ordinary skill to repeatedly advance the fiber device of Kittrell et al when it is inserted through the tubular member of Heaven, since Kittrell et al specify the device is to be advanced through the lumen until the obstruction is removed, thus producing method such as claimed.

Claims 13 and 14 are rejected under 3 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claim 12 above, and further in view of Vassiliadis et al. Vassiliadis et al teach the use of a gold coating on a laser applicator. It would have been obvious to the artisan of ordinary skill to employ a gold coating, as taught by Vassiliadis, since this would protect tissue from unintended irradiation, thus producing a device such as claimed.

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claims 17-21 are above, and further in view of Isner et al. Isner et al teach a method of treating tachycardia including inserting a catheter and inserting a fiber therein for applying laser energy to the foci responsible for the tachycardia. It would have been obvious to the artisan of ordinary skill to employ the tachycardia treatment method of Isner et al in the surgical device placement method of Heaven, since Heaven teach that the device can be used with a variety of medical procedures thus producing a method such as claimed.

Applicant has amended the claims to recite a tapered distal end. With the understanding that the originally submitted informal drawings render discerning the exact form of the various

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embodiments somewhat challenging, it appears that this limitation refers to the taper associated with the hour glass shape of figures 10 and 11, this presumed correct since claim 7, dependent on claim 1, recites the hour glass shape. However, Heaven teaches the concept of tapering (see Figure 5 and 6 and column 5, lines 51-63).

Applicant apparently argues that because the distal most portion of the tube of Heaven exhibits the full diameter thereof it cannot be considered to be a “tapered distal end” as claimed. The examiner once again notes that claim 7, which specifically recites “an hour glass shape from the distal end to said proximal end, said hour glass having at lease one narrow portion relative to said distal and proximal ends.”

(emphasis added) allows for a distal end which is expanded with respect to the narrow portion. It is further respectfully noted that as this claim depends from claim 1, which requires the deflection member have “a tapered distal end.” Thus claim 1 must encompass devices that, while containing a taper in the distal end, also have a portion more distal to the taper, which is expanded with respect thereto (as in applicant’s figures 10 and 11).

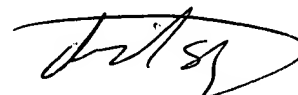
Applicant's arguments filed June 24, 2004 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

A handwritten signature in black ink, appearing to read 'D. Shay', enclosed within a large, loopy, oval-shaped flourish.

**DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330**